KDHE Standards For Protection Against Radiation

Part 6

Use of Radioactive Materials in the Healing Arts

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Objectives

- **Discuss WHEN and WHY the new Part 6 regulations were implemented**
- **A brief overview of 14 Subparts within Part 6**
- **Discuss the regulatory changes from the previous Kansas state regulations**

The NEW Part 6 – Use of Radioactive Materials in the Healing Arts

- KDHE adopted by reference in K.A.R. 28-35-264
- NRC Title 10 CFR Part 35 as in effect on May 2, 2005
- Went into effect December 30, 2005
- Why? To ensure compatibility with NRC regulations

Part 6 Consists of 14 Subparts – A through N

- **Subpart A – General Information**
  - **Implementation**
  - **License required**
  - **Applying for and amending the license**

Part 6 Consists of 14 Subparts – A through N

- **Subpart B – General Administrative Requirements**
  - **Authority and Responsibilities of the Radiation Safety Program**
  - **Supervision**
  - **Written Directives**
  - **Specific training requirements for RSO, Medical Physicist, and Nuclear Pharmacist**

Part 6 Consists of 14 Subparts – A through N

- **Subpart C – General Technical Requirements**
  - **Release of Patient Criteria**
  - **Decay in storage**

Part 6 Consists of 14 Subparts – A through N

- **Subpart D – Unsealed Byproduct Material – Written Directive Not Required**
- **Subpart E – Unsealed Byproduct Material – Written Directive Required**
- **Subpart F – Manual Brachytherapy**

Part 6 Consists of 14 Subparts – A through N

- **Subpart G – Sealed Sources for Diagnosis**
- **Subpart H – Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units**

Part 6 Consists of 14 Subparts – A through N

- **Subpart I – Reserved**
- **Subpart J – Training and Experience Requirements**
- **Subpart K – Other Medical Uses of Byproduct Material**

Part 6 Consists of 14 Subparts – A through N

- **Subpart L – Records**
- **Subpart M – Reports**
- **Subpart N - Enforcement**

Regulation changes in adopting Part 35

- Training requirements
- Patient release
- Decay in storage
- Medical event notification

SPECIFIC TRAINING REQUIREMENTS

- **35.50 – Radiation Safety Officer**
- **35.51 – Authorized Medical Physicist**
- **35.55 – Authorized Nuclear Pharmacist**

SUBPART B 35.50
Radiation Safety Officer

- **Certified by a specialty board whose certification process has been recognized by the state / NRC**
- **OR…**
- **200 hours of classroom and lab training**
- **One year full-time radiation safety experience under an RSO listed on a state license.**
- **OR…**

SUBPART B 35.50
Radiation Safety Officer

- **Is a medical physicist who has been certified by a specialty board and has license specific experience in radiation safety**
- **OR…**

SUBPART B 35.50
Radiation Safety Officer

- Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license with license specific experience in radiation safety
- Has obtained written attestation, signed by a preceptor RSO
- Has license specific training in radiation safety, regulatory issues, and emergency procedures

SUBPART B 35.51
Authorized Medical Physicist

- **Certified by a specialty board whose certification process has been recognized by the state/NRC**

- **OR…**

SUBPART B 35.51
Authorized Medical Physicist

- **Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics**
- **Completed 1 year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the license specific requirements for an authorized medical physicist.**

SUBPART B 35.51
Authorized Medical Physicist

- **Has obtained written attestation, signed by a preceptor authorized medical physicist**

- **Has license specific training. Can be either a training program provided by the vendor or training supervised by an authorized medical physicist**

SUBPART B 35.55
Authorized Nuclear Pharmacist

- Certified by a specialty board whose certification process has been recognized by the state/NRC
- OR…
- Has completed 700 hours in a structured educational program
  - 200 hours of classroom and lab training
  - Supervised practical experience in a nuclear pharmacy

SUBPART B 35.55
Authorized Nuclear Pharmacist

- **Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist**

SUBPART B
35.57- Training for experienced Radiation Safety Officer, Medical Physicist, Authorized User, and Nuclear Pharmacist.

- **Any individual identified above that is listed on a State of Kansas radioactive materials license prior to December 30, 2005, need not comply with the new training requirements of 33.50, 33.51, or 33.55.**

SUBPART B
35.59 – Recentness of Training

- **Training and experience must have been obtained within the 7 years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.**

Specialty Board(s) Certification Recognized by NRC Under 10 CFR Part 35

- **WHY!?!**

- **These Specialty Boards meet the certification criteria necessary to comply with the regulations set forth in PART 35**

Specialty Board(s) Certification Recognized by NRC Under 10 CFR Part 35

- http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html

NEW Training Requirements

- **Group I – Use of unsealed byproduct material for uptake, dilution, excretion studies for which a written directive is not required (35.100).**

- **Certified by a specialty board whose certification process has been recognized by the state/NRC (35.190)**
- **OR…**

NEW Training Requirements

- **Complete 60 hours of training and experience including 8 hours of classroom (35.190).**
- **Has obtained written attestation by an authorized user (35.190)**

NEW Training Requirements

- **Group II and Group III– Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required (35.200).**
- **Certified by a specialty board whose certification process has been recognized by the state/NRC (35.290)**
- **OR…**

NEW Training Requirements

- **Complete 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training (35.290).**

- **Has obtained written attestation by an authorized user (35.290)**

NEW Training Requirements

- **Group IV and Group V - Use of unsealed byproduct material for which a written directive is required (35.300).**

- **Certified by a specialty board whose certification process has been recognized by the state/NRC (35.390)**
- **OR…**

NEW Training Requirements

- **Complete 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training (35.390).**

- **Has obtained written attestation by an authorized user (35.390)**

NEW Training Requirements

- **Group VI- Use of sources and devices containing radioactive material used for medical diagnosis and therapy (35.400).**

- **Certified by a specialty board whose certification process has been recognized by the state/NRC**
- **OR…**

NEW Training Requirements

- **Complete 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training (35.490).**

- **Complete 3 years of supervised clinical experience in radiation oncology under an authorized user (35.490)**

NEW Training Requirements

- **Has obtained written attestation, signed by a preceptor authorized user**

SUBPART A
35.10 - Implementation

- **The training requirements, including recentness of training, shall be implemented on or before December 30, 2007.**

SUBPART C
35.75 – Release of individuals containing unsealed byproduct material

- A licensee may authorize the release from its control of any individual who has been administered unsealed byproduct material if the TEDE to any other individual from exposure is not likely to exceed 500 mR.
- NUREG 1556 Vol 9 Rev 1 Appendix U for patient release model procedure

SUBPART C
35.75 – Release of individuals containing unsealed byproduct material

- **A licensee shall provide the release individual, or individual's parent or guardian, instructions on actions recommended to maintain doses to others as low as reasonably achievable if the TEDE to any other individual is likely to exceed 100 mR.**

SUBPART C
35.75 – Release of individuals containing unsealed byproduct material

- **Release authorization is DOSE BASED.**

SUBPART C
35.92 – Decay-in-storage

- **Licensee may hold byproduct material with a physical half-life of less than 120 days for decay-in-storage before disposal without regard to its radioactivity provided…**

SUBPART C
35.92 – Decay-in-storage

- **The byproduct material radioactivity cannot be distinguished from background at it's surface with no shielding.**

- **An appropriate survey meter is used at it's most sensitive scale.**

SUBPART M
35.3045 – Report and notification of a medical event

- **A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 5 Rem effective dose equivalent, 50 Rem to an organ or tissue, or 50 Rem shallow dose equivalent to the skin.**